1642 #10 2/28/02 NA

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John O'Connor, et al.

Serial No.: 09/630,215 Group Art Unit: 1642

Filed : August 1, 2000 Examiner: G. Gabel

For : METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY Hcg ASSAY

1185 Avenue of the Americas
New York, New York 10036
January 10, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO SEPTEMBER 10, 2001 OFFICE ACTION AND PETITION FOR A THREE-MONTH EXTENSION OF TIME

This Communication is submitted in response to a September 10, 2001, Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the September 10, 2001 Office Action was originally due October 10, 2001. Applicants hereby petition for a three-month extension of time. Applicants have previously established small entity status. The required fee for a three month extension of time is $920.00 and authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125. Therefore, a response to the September 10, 2001 Office Action is now due January 10, 2002. Accordingly, this Communication is being timely filed.

Election/Restrictions

The Examiner required restriction to one of the following inventions under 35 U.S.C.121:

I. Claims 1-3, 6, 8, 14-15, 18, 20-21, 27-28, 31-32, 38-39, and 42, allegedly drawn to method of predicting the likelihood of a negative pregnancy outcome in a female subject and antibody for use thereof, classified in class 436, subclass 510.

II. Claims 44, 46, 49, and 51, allegedly drawn to method for detecting non-trophoplast malignancy in a sample, classified in class 435, subclass 7.92.

III. Claim 53, allegedly drawn to method for detecting gestational trophoblast disease, classified ni class 436, subclass 65.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons. The Examiner stated that inventions I, II, and III are unrelated. The Examiner stated that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects in that invention 1 sets forth a correlative relationship between the early pregnancy associated molecular isoform of hCG and normal pregnant female subject, Invention II sets forth a correlative relationship between the early pregnancy associated molecular isoform and intact non-nicked hCG ni a subject to detect non-tropoblast disease, and InventionIII sets forth a correlative relationship between the earaly pregnancy associated molecular isoform oh hCG and late pregnancy associated molecular isoform of hCG in a subject to detect gestational trophoblast disease. The Examiner stated that because these inventions are distinct for the reasons given above

and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because the search required for Group I is not required for Group II, and the search for Group II is not required for Group III, restriction for examination purposes as indicated is proper. Literature search for each method and apparatus is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

In response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, to prosecute the invention of Examiner's Group I, i.e. claims 1-3, 6, 8, 14-15, 18, 20-21, 27-28, 31-32, 38-39 and 42, allegedly drawn to a method of predicting the likelihood of a negative pregnancy outcome in a female subject and antibody use thereof.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction of Examiner's Group I from Examiner's Groups II to III be withdrawn in view of the fact that the claims of Examiner's Group I are not independent of Examiner's Group's II-III. Applicant maintains that the claims of Examiner's Group I and Examiner's Groups II-III do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group I allegedly drawn to a method of predicting the likelihood of a negative pregnancy outcome in a female subject and antibody use thereof are related to the claims of Examiner's Groups II to III in that the claims in all groups are related to the same antibodies.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, Applicant points out that M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

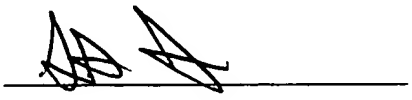
Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group I will reveal whether any prior art exists as to the claims of Examiner's Groups II and Group III. Since there is no burden on the Examiner to examine Groups I-III in the subject application, the Examiner must examine the entire application on the merits.

Applicant maintains that claims 1-3, 6, 8, 14-15, 18, 20-21, 27-28, 31-32, 38-39 and 42, 44, 46, 49, 51 and 53 define a single inventive concept. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-3, 6, 8, 14-15, 18, 20-21, 27-28, 31-32, 38-39 and 42, 44, 46, 49, 51 and 53 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone either of them at the number provided below.

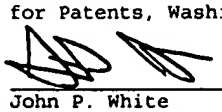
No fee, other than the $920.00 fee for a three month extension of time is deemed necessary in connection with the filing of this Communication and authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Spencer H. Schneider
Registration No. 45,923
Attorneys for Applicant(s)
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



1-10-02

John P. White Date
Reg. No. 28,678
Spencer H. Schneider
Reg. No. 45,923